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Process and device for the manufacture of a primary unit pack of a wafer

The invention relates to a process and a device for the manufacture of a primary unit pack of a wafer, particularly of a wafer that has been separated from an active substance film of one or more active substances for use as a dosage unit and administration form for medicaments.

Apart from the known dosage forms for medicaments, such as tablets, capsules, drops or similar administration forms, there is the administration form of the "wafer". This is a small thin plate of an active substance film comprising a predetermined amount of active substance and with a thickness and dimensions adapted according to the amount of active substance to be delivered. A wafer is flexible, soft, of small weight and can be torn. Since there is a direct correlation between the contact surface of the wafer and the dosage amount of the active substance, its dimensions must be identical to the greatest possible extent with the dimensions calculated, and must lie within the range of tolerance. Because the dosage is dependent on the surface area, the soft active substance material must not be stretched prior to cutting since otherwise the amount of active substance would be changed. For this reason, the manufacture of the wafer and the packaging of a single wafer or the packaging of several wafers in a primary pack unit is costly.

From DE 198 00 682 A1 there is known a process for the manufacture of a primary pack unit for film-like or wafer-like administration forms (wafers) for oral application, comprising one section of an upper packaging material web and one section of a lower packaging material web. When ap-

plied to square or rectangular wafers, the course of this process - which is in principle also applicable to unit packs of wafers - is different from that of the manufacture of wafers of another shape. For square or rectangular wafers, the first step is to convey an upper packaging material web and a lower packaging material web, without cold or hot forming, on top of one other via respective deflecting shafts, while the film-like or wafer-like administration form is simultaneously conveyed between the two webs of packaging material by means of rollers or gripper feed systems. In this process, it is also possible to feed an active substance film in the form of a web material - single-webbed or multi-webbed, parallel and spaced at a distance from one another - with the desired width of the dosage units. Subsequently, dosage units are singled out from the web-shaped active substance film by means of a cross-cutting apparatus which is positioned immediately in front of the deflecting shafts. In a further process step, the two webs of packaging material are sealed together with the help of a heated sealing tool in such a way that the single dosage units are sealed into compartments and are completely enclosed by sealed seams or sealed areas. In further process steps, perforations are punched between the compartments and primary pack units are partitioned off.

For wafers which are to have a shape other than square or rectangular, the process for the manufacture of the primary package unit according to DE 198 00 682 A1 is configured as follows: In a first process step, a laminate of the web-like active substance film and a carrier sheet is provided, out of which the dosage units are punched with a punching device in a further process step without punching through the carrier sheet. The partially punched laminate is subsequently rerouted over an edge or a deflecting shaft with the help of roller feed or gripper feed systems so that the

dosage units thereby become detached from the carrier sheet. If necessary, an additional stripping device can be used for this purpose. Thereafter, an upper web of packaging material and a lower web of packaging material without cold or hot forming are conveyed on top of one another by means of respective deflecting shafts, whereby the dosage units becoming detached from the carrier sheet are simultaneously conveyed between the two webs of packaging material. Subsequently, the two webs of packaging material are sealed together with the help of a heated sealing tool in such a way that the single dosage units are sealed into compartments and are completely enclosed by sealed seams or sealed areas. In further process steps, perforations are punched between the compartments and primary packaging units are partitioned off. It goes without saying that this process can also be applied to the manufacture of square or rectangular wafers and the packaging thereof in primary unit packs.

Also known from the aforementioned DE 198 00 682 A1 are devices for carrying out the respective processes. One of these devices has a supply device for a laminate made up of an active substance film and a carrier sheet, a cutting or punching device for the active substance film for punching a wafer on the carrier sheet, a separating tool for detaching the active substance film from the carrier sheet, a pulling device for the carrier sheet, and thereby also for the active substance film with the wafer, a packaging material feeding and packaging material pulling device for two webs of packaging material which receive the respective wafer, a heated sealing tool for the packaging material, and a cutting tool for separating the sealed pouch.

The wafer material is elastic and may, as a consequence of the mechanical stress occurring when it is transported be-

tween the upper packaging material web and the lower packaging material web, change its shape and its dimensions, there being a risk of the amount of active substance in the single wafer changing as well since the area of the wafer is decisive for dosing the active substance. With the above described processes it is not possible to ensure the required constancy of the active substance amount since the wafer material is in each case subjected to mechanical stress prior to being inserted between the packaging material webs.

It is the object of the invention to configure a process and a device for the manufacture of a primary unit pack of a wafer according to the introductory part of claim 1 and the introductory part of claim 6 such that the wafer material is not subjected to mechanical stress.

This object is achieved in a process according to the introductory part of claim 1 and in a device according to the introductory part of claim 6 by the respective characterizing features of said claims. Advantageous embodiments are indicated in the respective sub-claims.

The process according to the invention consists in that a laminate made up of a carrier sheet and an active substance film is provided and pulled off, the carrier sheet becoming detached from the active substance film in the process and being separately wound up. Due to the forward motion of the carrier sheet, the active substance film is also moved forward. With its front end, the active substance film is conveyed, without mechanical stress, between two resting packaging material webs, is fixed by said packaging material webs and in order to produce the wafer is crosscut at a predetermined rearward distance from the packaging material webs. Subsequently the wafer, which is fixed between the

packaging material webs, is pulled forward, together and synchronously with said webs, whereby the pulling force acts on the packaging material webs, and is fed to a sealing station. In this sealing station, the packaging material webs are sealed, outside of the area where the wafer is placed, to form a pouch or bag which is subsequently separated from the packaging material webs.

The laminate is produced in a known manner by using a coating process, and is subsequently cut into strips which are coiled up; the width of a coil corresponds to the width of the desired wafer or to a multiple of said width of the wafer. If a plurality of wafers is cut from the coil, the individual wafers are spread out so as to be arranged over the width necessary for inserting them in the packaging material webs. The coil is provided as a supply coil. The special advantage of this process is that the wafer is conveyed and guided without mechanical stress. The process is carried through in such a way that the respective length by which the carrier sheet, and thereby also the active substance film, is pulled forward corresponds to the desired length of a wafer, so that the wafers can be reproduced in an extremely precise manner and are always the same. As a consequence, each wafer also has the same active substance dose. Thereafter, the single wafer is fixed over its entire extent between the packaging material webs while said webs are being pulled forward, and it is not subjected to mechanical stress in the process. When the packaging material webs are sealed to form a bag, there is no risk of damaging the wafer fixed between said webs. The process is easily accomplished.

In a preferred embodiment, the active substance film, which has been detached from the carrier sheet, is conveyed in vertical orientation between the packaging material webs,

which in this process step are in a resting condition and arranged at a distance from each other. The packaging material webs are subsequently put against the wafer and are pulled forward on both sides of the active substance film, at the same speed of pulling and in the same direction of pulling so that the active substance film between the packaging material webs is pulled forward along with them without being subjected to mechanical stress. At the infeed of the active substance film the packaging material webs are guided through a clamping device which presses the packaging material webs against the wafer and fixes them; this takes place at the end of the work cycle, during which the active substance film has been placed with its front end between the packaging material webs. A relative motion between the wafer and the webs of packaging material is thus impossible. In this position, the active substance film is crosscut at a predetermined distance from the clamping station in order to separate a wafer, and in the next operational step is drawn between the packaging material webs and pulled forward along with them, completely and without being subjected to stress.

The device for carrying out the process comprises, in a known manner, a supply device for the laminate, which laminate is formed of a carrier sheet and an active substance film; a separating tool for detaching the active substance film from the carrier sheet; a pulling device for said carrier sheet and thereby for the active substance film as well; a cutting tool for said active substance film; a device for feeding the packaging material and pulling it forward, for two packaging material webs, which may be taken from a packaging material roll and be separated by means of a separating method and deflected; a heated sealing tool for the packaging material; and a cutting tool for separating the finished side-sealed bag. In accordance with the

invention, the device for feeding and pulling the packaging material is provided with a receiving and clamping device for the front end of the active substance film, which device is arranged in vertical direction below the separating tool for detaching the active substance film and below the cutting tool for said active substance film, in such a way that during a feed cycle the active substance film, which has been detached from the carrier sheet, moves downwards in vertical direction into the receiving and clamping device. During this process the active substance film is not subjected to mechanical stress.

The receiving and clamping device is preferably formed of clamping rolls between which the packaging material webs are guided under tension and which are movable in horizontal direction and thereby transversely to the direction in which the active substance film is pulled forward, in opposite direction to each other, between a receiving position for receiving the active substance film and a clamping position for clamping the active substance film. To form an infeed funnel for the active substance film, two pairs of clamping rolls may be arranged one above the other.

In the following, the invention will be explained by means of an example of an embodiment. The accompanying drawings are schematic representations of:

Fig. 1: a device for the manufacture of a primary unit pack of a wafer, and

Figs. 2 to 5: an associated receiving and clamping device of the wafer, in successive process steps.

The device shown in Fig. 1 is provided at its entry side with a supply roll 1 with a laminate 4, made up of a carrier sheet 2 and an active substance film 3, which is to be

pulled forward; a deflecting roll 5 and a stripping device 6 for detaching the active substance film 3 from the carrier sheet 2; and a coil 8 for winding up the carrier sheet 2. Below the separating roll 7, there are arranged guide paths or guide bars 9 for exact alignment of the active substance film 3, which has been detached from the carrier sheet 2, a crosscutting device 10 with a knife (not shown), and a device 11 for feeding and pulling the packaging material, for two packaging material webs 12, which device 11 on the side of the cutting device has a receiving and clamping device formed of two pairs of clamping rollers 13 and 14 which are arranged one above the other. The packaging material webs 12 are arranged on supply rolls 15 and are guided via the clamping rollers 13 and 14 to the pulling rolls 16, by means of which they are fixed by clamping and pulled forward, as a consequence of which they are also lying, under tension, on the clamping rollers 13 and 14. Between these rollers (13, 14) and the pulling rolls 16 there are arranged heated cross-sealing and longitudinal-sealing tools 17 and 18, and in the direction of pulling, following the pulling rolls 16, a flat knife 19 as a cutting device.

To manufacture a primary unit pack of a wafer, a laminate 4, which has the predetermined width of the wafer, is drawn off, by the predetermined length of the wafer, from the supply coil 1 by actuating the coil 8. In this process, the active substance film 3 is removed from the carrier sheet 2 by means of the separating roll 7, and is oriented downwards in vertical direction by the guide paths or guide bars 9, said guide paths or bars not possessing any clamping function for clamping the active substance film 3. In this process, the front end of the active substance film 3 moves between the clamping rollers 13 and 14, which are in their receiving position at a distance from each other and

along which on the side of the active substance film the packaging material webs 12 are guided and, in the receiving position, rest against said rollers under tension. In the preceding cycle the packaging material webs 12 have been provided with a transverse sealed seam 20 which now forms the front or bottom seam of the side-sealed bag, that is, of the primary unit pack of the wafer, which is being produced. This process step is depicted in Fig. 2. In the next process step (Fig. 3) the packaging material webs 12 are pressed by means of the clamping rollers 13, 14 against the front region of the active substance film 3 which has been pulled forward and this active substance film is fixed between the packaging material webs 12 by the said rollers (13, 14) being moved towards each other. A wafer 21 of the predetermined length is now separated from the active substance film 3 by the crosscutting device 10. Thereafter, the packaging material webs 12 are pulled forward, along with the wafer clamped between them, by synchronous actuation of the pulling rolls 16, to the position of the rearward transverse sealed seam (Fig. 4), the wafer 21 being moved free of friction and at the same speed as the packaging material webs 12. In this position the packaging material webs 12 are heat-sealed with each other on the two longitudinal sides by the two longitudinal-sealing tools 18 and on the rearward transverse side by the transverse-sealing tool 17. The width of the resulting transverse sealed seam is selected such that it can be divided crosswise and forms both the sealed seam of the primary unit pack which has just been manufactured, but which has yet to be separated, and the front or bottom seam of the following unit pack. After sealing, the clamping rollers 13, 14 are moved back to their receiving positions and are thereby opened. This process step is shown in Fig. 5. The next cycle again starts with inserting the active substance film between the clamping rollers 13 and 14, which are in the

receiving position, as described above. After each cycle, a primary unit pack 22 of a wafer 21 - which unit pack has been manufactured in the above-described manner - is separated by the flat knife 19 from the following unit pack.

LIST OF REFERENCE NUMERALS

1 supply coil
2 carrier sheet
3 active substance film
4 laminate
5 deflecting roll
6 stripping device
7 separating roll
8 coil
9 guide paths or guide bars
10 crosscutting device
11 device for feeding and pulling the packaging material
12 packaging material web
13 clamping roller
14 clamping roller
15 supply roll
16 pulling roll
17 transverse-sealing tool
18 longitudinal-sealing tool
19 flat knife
20 transverse sealed seam
21 wafer
22 unit pack